DEPARTMENT OF HEALTH AND HUMAN SERVICE

94544

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

February 20, 2004

WARNING LETTER NO. 2004-NOL-15

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Henri M. Rathle, President/Co-Owner
Gumbo Brothers Inc., d.b.a. Azalea Seafood Gumbo Shoppe
5570 Peary Road
Theodore, Alabama 36582

Dear Mr. Rathle:

On October 16, 17, and 21, 2003, we inspected your firm, located at 5570 Peary Road, Theodore, Alabama. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123) and the Current Good Manufacturing Practice (CGMP) requirements for foods, 21 CFR 110. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of 21 CFR 123, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your seafood products, including seafood gumbo, shrimp creole, crawfish etouffee, and shrimp and crabmeat bisque, are adulterated in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at http://www.fda.gov.

The deviations are as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as any "biological, chemical or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for seafood gumbo, bisque, shrimp creole and crawfish etouffee does not list the hazard of undeclared sulfites. We note that some of your products declare, "may contain sulfites," however, there is no control listed in your HACCP plan for undeclared sulfites.

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met at each of the critical control points in order to comply with 21 CFR 123.6(c)(3). A critical

limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for seafood gumbo, bisque, shrimp creole and crawfish etouffee lists a critical limit, [redacted] that is inadequate to control the hazard of pathogen survival. You must list a cook time that is adequate to control pathogens, such as *Listeria monocytogenes*, at the coldest point of your product. The monitoring and record keeping method listed in your HACCP plan should adequately describe how you will accomplish this, e.g. "continuous monitoring of temperature," or "measure time at full boil" and "daily processing log." The frequency should be listed as "every lot" or "every batch." Additional information regarding the control of pathogen survival during cooking can be found in chapter 16 of FDA's *Fish and Fisheries Products Hazards and Controls Guidance*: http://www.cfsan.fda.gov/~comm/haccp4.html.

- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the prevention of cross contamination and exclusion of pests with sufficient frequency to ensure control as evidenced by the fact that:

  1. Several gaps were observed in the exterior doors of the building providing a path directly into the processing area. On October 16, 2003, our investigator documented at least 10 live flies, one live centipede, and two dead roaches in your firm during processing operations; and,

  2. Portions of a metal vent hood were observed to be rusted and flaking. This hood is located directly above an area where seafood stock is cooked. On October 16, 2003, our investigator observed a pot of shrimp stock cooking directly below this hood. The shrimp stock was later used in the manufacture of seafood gumbo.

We may take further regulatory action if you do not correct these violations promptly. For instance, we may seize your product(s) and/or enjoin your firm from operating.

We are aware that at the close of the inspection, on October 21, 2003, Mr. Mark A. Battle, Manager, made verbal commitments to correct the observed deficiencies. We also are aware that at the close of the October 11, 15-17, 2001, inspection, Mr. John D. Addison, Vice President/Co-Owner, made verbal commitments to correct the observed deficiencies from that inspection, and at least one of those deficiencies is similar to the one we observed in our most recent inspection. Please respond in writing, within fifteen (15) working days from your receipt of this letter. Your response should outline specific actions you are taking to correct the deficiencies. You should include in your response documentation such as copies of HACCP plans, HACCP monitoring records, and other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and

the CGMP regulations in manufacturing, packing, or holding food for human consumption. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483